IN THE UNITED STATES DISTRICT COURT DISTRICT OF SOUTH CAROLINA CHARLESTON DIVISION

United States of America, et al.,) Civil Action No. 9:14-cv-00230-RMG
Plaintiffs,) (Consolidated with 9:11-cv-1593-RMG and) 9:15-cv-2458-RMG)
ex rel. Scarlett Lutz, et al.,	ORDER and OPINION
Plaintiffs-Relators,)
v.)
Berkeley Heartlab, Inc., et al.,)
Defendants.)
)

This matter is before the Court on Defendant Floyd Calhoun Dent, III's motion to compel the Government to provide complete production with respect to several of his Requests for Production ("RFPs"), including RFP Nos. 1-11, 14-21, 23-31, 33-48, 51-52, 54-55, 57-58, 60-61, 67, 69-70, 72-73, 75-80, 83-86. (Dkt. No. 351 at 6.) For the reasons set forth below, the motion to compel is granted in part and denied in part.

I. Background

The Government has filed a complaint in intervention against Defendants BlueWave Healthcare Consultants, Inc. ("BlueWave"), Floyd Calhoun Dent, III, LaTonya Mallory, Robert Bradford Johnson, and others alleging violations of the Anti-Kickback Statute ("AKS"), 42 U.C.S. § 1320(a)-7b(b)(1)(A) and False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"). (Dkt. No. 75.) The alleged FCA violations arise from BlueWave's marketing of laboratory tests for two laboratory companies, Health Diagnostic Laboratory, Inc. ("HDL") and Singulex, Inc. ("Singulex"), between 2010 and 2014. The Government has alleged that Defendants violated the FCA when

they orchestrated multiple kickback schemes to induce physicians to refer blood samples to HDL and Singulex for large panels of blood tests, many of which were medically unnecessary. The Government alleges that the kickback schemes violated the Anti-Kickback Statute, resulted in false claims submitted to the Medicare and TRICARE programs, and caused the Government to pay HDL more than \$330 million.

II. Legal Standard

Rule 26(b)(1) of the Federal Rules of Civil Procedure outlines the scope of discovery in a civil case:

[U]nless otherwise limited by court order, the scope of discovery is as follows: Parties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense and proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

Rule 34 allows a party to serve on another party a request for production as to any matter "within the scope of Rule 26(b)" as outlined above. Fed. R. Civ. P. 34(a). Parties' objections to document production requests must be stated with particularity and specificity; objections may not be "boilerplate." Fed. R. Civ. P. 33(b)(4). "A party must produce documents as they are kept in the ordinary course of business or must organize them to correspond to the categories in the request." Fed. R. Civ. P. 34(b)(2)(E)(i). Rule 37(a)(3)(B) allows a party seeking discovery to move for an order compelling production or answers against another party when the latter has failed to produce documents requested under Rule 34. Fed. R. Civ. P. 37(a)(3)(B)(iii)-(iv). "[A]n evasive or incomplete disclosure, answer, or response must be treated as a failure to disclose, answer, or respond." Fed. R. Civ. P. 37(a)(4).

III. Discussion

I. Organization / Labeling of Documents

Dent asserts that the Government has unfairly failed to organize and label documents to clearly indicate which documents it has produced in response to each particular RFP. (Dkt. No. 383 at 2.) The Government argues that doing so would be unduly burdensome for the over 2 million pages of documents it has produced. The Court is concerned that the Government is comfortable claiming that it has fully complied with a number production requests while at the same time arguing that it would be "impossible" for it to produce a record of which documents it has produced in response to each RFP. (Dkt. No. 380 at 5.) It is reasonable and fair for the Government to make clear which documents it is producing in response to which RFP. Dent has indicated that an index of which Bates-numbered documents are responsive to each RFP would be an appropriate approach (Dkt. No. 383 at 3), and this Court agrees. The Government is therefore ordered to produce an index of which Bates-numbered documents it has produced in response to each RFP.

II. Privilege Log

The Government shall also file a complete privilege log for all responsive documents it has withheld on any privilege-related ground.

III. The Government's General Objections

This Court finds the following with regard to the Government's General Objections (Dkt. No. 351-2):

General Objection No. 3: For the reasons listed in Dent's motion to compel (Dkt. No. 351 at 7), this Court agrees that the terms "Government," "Plaintiff" and "USA" are reasonably interpreted to include those components of the federal government directly connected to the United States'

Complaint in Intervention. The Government is therefore ordered to use the following terms to identify responsive documents if it has not already done so: Medicare Part B Program; Tricare Program; U.S. Department of Health and Human Services ("HHS"); HHS' Office of Inspector General ("OIG"); HHS' Center for Medicare and Medicaid Services ("CMS"); U.S. Attorney's Offices ("USAOs"); U.S. Department of Justice ("DOJ"); and the Federal Bureau of Investigation ("FBI").

General Objection No. 4: The government objects to the terms "opined on the legality," and "opined that" as vague, misleading or overbroad. The Court need not determine whether these terms are vague as it has denied the motion to compel with respect to RFP No. 30, below.

General Objection No. 11: The Government has objected to the RFPs to the extent they seek documents received from, or communications exchanged with, Relators or their counsel because such documents and communications are "protected by the attorney-client, attorney work-product, investigative files, law enforcement privileges, and the joint prosecution/common interest doctrines." (Dkt. No. 351-2 at 4.) Dent reported that the Government was nonetheless planning to produce the relevant Relators' documents. (Dkt. No. 383 at 7.) For this reason, the Court takes no position at this time on General Objection 11 and the motion to compel as to RFP Nos. 4, 5, and 21 is denied at moot but without prejudice.

General Objection No. 12: The Government has objected to any RFP that requests "information concerning the Government's investigation of this matter including, but not limited to, the Government's investigative efforts, its assessments of the facts and allegations in this case, and its deliberative processes concerning actions taken regarding this matter." The Court addresses privilege issues with particular RFPs below so need not address the Government's general objection here.

General Objection No. 13: The Objection is not stated with particularity. If the Government wishes to withhold documents on the grounds that any RFP is "based upon inaccurate assumptions or misstatements of fact or law," it must identify the RFP and explain the purported misstatements.

General Objection No. 15: This Objection is not stated with particularity. If the Government wishes to withhold documents on the grounds that any RFP "misrepresents or mischaracterized the Government's Complaint," it must specifically identify such misrepresentations or mischaracterizations.

General Objection No. 17: The Government has objected to the RFPs to the extent they seek unlimited information about or belonging to Berkeley or Quest because it is not seeking liability from Dent, Johnson, or BlueWave for claims made by Berkeley or Quest. Dent appears to agree and "waives the part of the RFP requesting information about Berkeley and Quest." (Dkt. No. 351 at 9.) No further intervention from the Court appears necessary as the Government's Objection No. 17 pertained only to Berkeley and Quest.

General Objection No. 18: This Objection is not stated with particularity. If the Government wishes to withhold documents which it believes are already in the possession of Dent, Johnson, or BlueWave, it must identify those documents.

General Objection No. 20: The Government has objected to the phrase "lab industry standards relating to the payment of P&H fees" on the grounds that it is vague and ambiguous. The Government has assumed that the phrase is used to mean the laws implicated by the practice of the payment of P&H fees to physicians. The Court agrees with Dent that the Government's interpretation is too narrow because a plain reading of the term encompasses information beyond the laws implicated by the payment of P&H fees to physicians (e.g., P&H contracts, marketing, and fee rates).

The Government is hereby ordered to respond to any RFPs containing this term in a manner consistent with the Court's interpretation.

IV. Specific Requests for Production

RFP No. 3: Dent's RFP No. 3 seeks "all witness statements of any kind related to this action, including all written, transcribed, and/or recorded statements, as well as all memorandums of interviews, notes of interviews, FBI 302 reports, etc., relating to any witness." The Government reports that it has already produced all sworn or verbatim statements (e.g., deposition testimony) from Leonard Blasko, Dr. Lloyd Miller, Gary Tom, and Tony Carnaggio and claims that any other responsive law enforcement memoranda of witness interviews are privileged or protected by the work product doctrine, as are other memoranda and notes that discuss the witness interviews and statements. (Dkt. No. 380 at 7.)

In *United States ex rel. Landis v. Tailwind Sports Corp.*, the United States District Court for the District of Columbia explained that witness statements given to criminal investigators "provide the witnesses' initial, unadorned testimony on the key issues; and reveal how the witnesses' testimony and recollections may have changed over time. For those reasons, they are unique sources of both affirmative evidence and impeachment material for which there is no substitute. Particularly in *qui tam* actions, fairness dictates that both sides have equal access to relevant witness statements developed by law enforcement in prior or parallel criminal investigations." 303 F.R.D. 419, 426 (D.D.C. 2014) (granting motion to compel interview memoranda containing fact work product for interviews conducted during criminal investigation of *qui tam* allegations). Dent claims that the *Landis* decision supports his argument that the memoranda are discoverable. The Government, in turn, claims that *Landis* supports its position.

Landis, properly read, supports the United States' position that the witness interviews in this case should not be compelled. . . . The Landis court held that the memoranda summarizing witness interviews during the civil investigation "contain[] facts elicited

in the course of a litigation-related investigation that necessarily reflect[] a focus chosen by the lawyer and thus constitute opinion work product entitled to privilege," and therefore declined to compel them. *Id.* at 432 (internal quotations omitted). The court went on to hold that the memoranda prepared during the preexisting criminal investigation, however, were merely fact work product and the defendant had established a substantial need for them.

Unlike Landis, in the instant case there was no separate preexisting criminal investigation. Relators' qui tam complaints triggered the civil investigation that led directly to the United States' Complaint in Intervention. The civil "litigation-related investigation" was driven by the Government's civil counsel from the very beginning, notwithstanding any parallel criminal matter, "as part of their efforts to determine whether to intervene in this litigation." Id. at 432. All witness interview memoranda as well as attorney notes reflecting witness statements are therefore opinion work product and the Court should deny Dent's Motion to Compel them on that ground alone.

(Dkt. No. 380 at 8-9.) The Government appears to argue that no criminal investigation took place or that, if it did, all documents in connection with that investigation are privileged because their creation was "driven by the Government's civil counsel." The government provides no legal basis for extending the work product protection so broadly.

Under Rule 26(b)(3) of the Federal Rules of Civil Procedure, materials that are "prepared in anticipation of litigation or for trial by or for [a] party or its representative," are protected from discovery. Fed. R. Civ. P. 26(b)(3). A party may to discover work product and documents prepared in anticipation of litigation or for trial by another party's attorney or agent if "(i) they are otherwise discoverable under Rule 26(b)(1); and (ii) the party shows that it has substantial need for the materials to prepare its case and cannot, without undue hardship, obtain their substantial equivalent by other means." Fed. R. Civ. P. 26(b)(A).

Opinion work product contains an attorney's opinions, legal theories, mental impressions, or conclusions. *In re Grand Jury Proceedings* # 5, 401 F.3d 247, 250 (4th Cir. 2005). Fact work product generally consists of "substantially verbatim witness statements contained in interview memoranda that have not been sharply focused or weeded by an attorney." *United States ex rel.*

Cairns v. D.S. Med., L.L.C., No. 1:12CV00004 AGF, 2016 WL 7437919, at *5 (E.D. Mo. Dec. 22, 2016) ((quoting United States v. Clemens, 793 F. Supp. 2d 236, 252 (D.D.C. 2011) (internal quotation marks omitted.) Fact work product is discoverable if a party establishes a substantial need for the materials and that he cannot obtain a "substantial equivalent" by other means. Id. at *5. For the reasons cited in Landis, discussed above, Dent has shown a substantial need for these materials.

The Government is therefore ordered to produce interview notes, memoranda, and other documents responsive to RFP. No. 3. The Government must log each responsive document it withholds from production as protected opinion work product. Dent will then have the opportunity to move to compel the production of any documents it believes the Government has improperly withheld as opinion work product.

RFP Nos. 18, 19, 21: These RFPs pertain to settlement discussions between the Government and certain parties, including HDL and Singulex. The Government has produced the formal settlement documents relevant to this case but objects to Dent's motion to compel production of additional settlement documents on the grounds that such requests are "irrelevant, unduly burdensome, disproportionate to the needs of the case and intrude upon the protections of FRE 408, attorney-client privilege, work product, and Government privileges." (Dkt. No. 380 at 16.)

Dent claims that the settlement discussions may be relevant because they "will likely show discussions or statements of: ambiguity of the interpretation of AKS Statute by lawyers for both the Government and the settling labs and individuals; the extent of penalties related to the underlying conduct; the extent of damages related to the underlying conduct; the allocation of damages to the underlying conduct; set-off of damages; the application of the June 25, 2014 Special Fraud Alert to the underlying conduct; the extent of scienter to violate the False Claims Act or AKS

Statute attributable to the BlueWave defendants, their lab principals; the potential waiver or declination of criminal sanctions against the settlors; the identification of witnesses and their potential testimony; settlors' cooperation with the Government against the BlueWave defendants; etc...." (Dkt. No. 383 at 11.) Courts in the Fourth Circuit have "generally declined to recognize a federal settlement privilege." *Townsend v. Nestle Healthcare Nutrition, Corp.*, No. 3:15-CV-06824, 2016 WL 1629363, at *5 (S.D.W. Va. Apr. 22, 2016) (listing cases) Because settlement discussions may be relevant to the issue of damages¹, the Government is hereby ordered to produce the settlement documents.

RFP Nos. 24-28, 54-55, 57-58, 60-61, 67, 72 and 80 (Expert Requests): Dent has withdrawn the portions of his motion to compel with respect to these RFPs to the extent they were related to expert witness documents². (Dkt. No. 383 at 11; Dkt. No. 380 at 19-20.)

RFP No. 30: Dent seeks documents in which "any attorney, law firm and/or Government agency had opined on the legality of the payment of P&H fees to physicians by any lab, including but not limited to Berkeley, HDL, Singulex, and Quest." The Government claims, and Dent does not disagree, that this request overlaps with RFP Nos. 6, 7, and 75 and is unique only insofar as it seeks communications of Government attorneys and of Government agencies. (Dkt. No. 380 at 11; Dkt. No. 383 at 5-6.) The Government claims that such communications are privileged, disproportionate to the needs of the case, and irrelevant. Dent claims that these documents are relevant because they may be consistent with his defense that his belief that the P&H fees were legal was reasonable because the AKS is ambiguous. Dent has not made a compelling case for why the Government's internal communications are relevant to Dent's or

¹ The Court takes no position at this time on whether the settlement discussions are relevant to any issue other than damages.

² The Court considers RFP No. 23 to fall within the category of expert requests as well.

any BlueWave Defendant's state of mind at the time of the conduct at issue. Dent suggests there may be other documents in the vein of the Special Fraud Alert that pertain to the lawfulness of P&H fees. (Dkt. No. 383 at 6.) The Special Fraud Alert is publicly available, and the Government has already agreed to produce relevant publicly available documents. In any event, Dent has not convinced the Court that the Government has waived its privilege with regard to these documents. The motion to compel as to RFP No. 30 is therefore denied.

RFP No. 31: Dent seeks "all documents relied upon or considered by the OIG in determining to issue the" Special Fraud Alert. The Government claims that these documents are protected by the deliberative process privilege. Three procedural steps are required to assert the deliberative process privilege. Hugler v. Bat Masonry Co., Inc., No. 6:15-CV-28, 2017 WL 1207847, at *3 (W.D. Va. Mar. 31, 2017) ("There are three procedural requirements for assertion of the privilege: 1) the agency head must assert the privilege after personal consideration; 2) the agency head must state with particularity the information subject to the privilege; and 3) the agency must aver precise and certain reasons for preserving the confidentiality of the requested documents.") The Government must also show that the documents it seeks to withhold based on the privilege are both predecisional and deliberative. Id.

Dent claimed that the government had not satisfied these procedural requirements. (Dkt. No. 383 at 6.) The Government has since³ complied with the procedural requirements. (Dkt. No. 426-2.) In her Declaration, Martha J. Talley asserts the privilege, states the information subject to the privilege (i.e., the language of Dent's RFPs), and provides reasons for preserving the confidentiality of the requested documents. An affidavit in support of withholding information based on the deliberative process privilege may not always be effective if, as here, it claims that

³ The Government filed the required affidavit with the Court on April 25, 2017.

every single document that is potentially responsive to the request is protected by the privilege. See Hugler at *3 (explaining the types of documents that do not qualify as both predecisional and deliberative). In this case, however, Dent has drafted his production requests to specifically target predecisional deliberations about the decision to issue the Special Fraud Alert. Dent's motion to compel as to the RFPs concerning the Special Fraud Alert is therefore denied without prejudice. As this RFP targets privileged information to begin with, the Court will not compel the Government to complete a privilege log. If Dent believes there are documents that are not predecisional and deliberative that would be relevant to his case or that he can overcome the privilege by showing that his need for the documents outweighs the potential harms of disclosure, he may file a new motion to compel.

RFP Nos. 33, 34, 36-48: The Government agreed to produce documents that are responsive to these RFPs. The motion to compel is therefore denied as most with regard to these documents. (Dkt. No. 383 at 11; Dkt. No. 380 at 22.)

RFP No. 51: Dent has moved to compel the Government to identify and produce documents demonstrating that the United States "has mitigated or has attempted to mitigate its damages related to this action." Both parties appear to agree that the requested mitigation documents are irrelevant to the FCA claims here. Whether mitigation evidence is relevant to the Government's alternative common law claims of Payment by Mistake of Fact (Count IV) and Unjust Enrichment (Count V) is a closer question. Dent has cited two cases which suggest that the Government could have a duty to mitigate damages in connection with these claims. *Jordan v. Northrop Grumman Corporation*, 2002 WL 35454612 (C.D. Cal. Aug. 5, 2002) (rejecting the

⁴ The Court has regretfully observed that the parties appear to enjoy churning the sea of discovery and drafting motions to document their efforts. The Court expects the parties to diligently attempt to reach agreement on all discovery disputes.

government's argument that "the duty to mitigate does not arise after the event causing the

payment has been committed" and finding that the Government may have a duty to mitigate

damages with respect to payment by mistake and unjust enrichment claims in the FCA context);

United States ex rel. Landis v. Tailwind Sports Corp., 308 F.R.D. 1, 6-7 (D.D.C. 2015) (denying

the Government' motion to strike defendants' affirmative defense that the Government failed to

mitigate its damages "in light of the high bar for striking a defense and the conflicting, non-

binding authority on this issue.") For this reason, the Court finds that the Government must

produce mitigation evidence that may be relevant to Counts IV and V.

V. Third-Party Documents

The Government has reported that it has made substantial progress producing third-party

documents and is coordinating with the various third parties to continue to make productions.

(Dkt. No. 380 at 26.) For this reason, the motion to compel is denied without prejudice with

regard to these documents. To the extent Dent believes the Government has not produced

relevant third-party documents, it may file a new motion to compel so the parties can brief the

specific legal issues relevant to those documents.

VI. Conclusion

For the reasons outlined above, Dent's Motion to Compel (Dkt. No. 351) is granted in

part and denied in part. The Government is hereby ordered to respond to Dent's RFPs in a

manner consistent with the Court's findings in this Order.

AND IT IS SO ORDERED.

The Honoral Richard Mark Gergel United States District Court Judge

April 27, 2017

Charleston, South Carolina

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